FEB 0 4 2002

BERCHTOLD®

K013668

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document are accurate and complete to the best of Berchtold Corporations knowledge.

Applicant:
Berchtold Corporation
1950 Hanahan Rd.
Charleston, SC 29406
843 569 6100

Contact:
Marika Anderson
Consultant, Tomami Ltd.
590 Crosby St.
Altadena, CA 91001
626 398 8934

Device Identification:

Common Name: Electrosurgical Cutting and Coagulation Device and Accessories
Trade Name: BERCHTOLD ELEKTROTOM®106 HiTT®

Indication: The BERCHTOLD ELEKTROTOM®106 HiTT® is intended for the coagulation of soft tissue during percutaneous, laparoscopic and intraoperative surgical procedures.

Device Description: The BERCHTOLD ELEKTROTOM®106 HiTT® is an electrosurgical system consisting of a high frequency energy generator, syringe pump, needle applicators and accessories.

Substantial Equivalence: The BERCHTOLD ELEKTROTOM®106 HiTT® is substantially equivalent to the predicate device since the basic features and design are similar and the intended uses are identical. The minor differences between the BERCHTOLD ELEKTROTOM®106 HiTT® and the predicate device raises no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Signed: Marika Anderson

Marika Anderson,
Consultant, Tomami Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 4 2002

Berchtold Corporation
c/o Ms. Marika Anderson
Tomami, Inc.
590 Crosby Street
Altadena, California 91001

Re: K013668
Trade/Device Name: ELEKTROTOM® 106 HiTT® System
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 31, 2001
Received: November 6, 2001

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013668

510(k) Number (if ~~known~~):

Device Name: ELEKTROTOM®106 HiTT® System

Indications for Use: This device is intended for the coagulation of soft tissue during percutaneous, laparoscopic and intraoperative surgical procedures.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013668

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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